

**From the President
Professor Dame Anne Johnson**

19 April 2021

Anne Marie Morris MP
Chair
All Party Parliamentary Group on Access to Medicines and Medical Devices

Dear Anne Marie Morris,

I am writing to you as the President of the Academy of Medical Sciences regarding the open call for evidence from the APPG on Access to Medicines and Medical Devices on *Post Brexit and Post Covid Reviews and Consultations - are we going far and fast enough? Part B: MHRA – a new role as an international regulator.*

The Academy of Medical Sciences promotes advances in medical science, and works to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost medical science experts drawn from academia, industry, and the health and care system.

We welcome the opportunity to support this important piece of work by the APPG. To ensure patients benefit from new medical innovations and to attract investment and promote innovation, the UK requires a regulatory system that is pragmatic, flexible, efficient, interactive and driven by public interest.

We would be very happy to expand on the points outlined below or provide further evidence as requested and look forward to remaining engaged with the APPG's work in this area, including Part C of this call for evidence.

Yours sincerely,



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Ensuring patients are at the centre of decision-making

While there is a strong economic incentive to ensure that the UK is an attractive market for companies wishing to licence their medicines, the priority for the MHRA should be ensuring patients have timely access to safe and effective medicines and healthcare products. Any strategy developed for the purpose of achieving competitive advantage should not risk these important factors.

In order to place improvements in patient health and care at the forefront of any changes to regulatory procedures, it is critical to use patient and public involvement as a means to understand the needs and priorities of patients. As such, the Academy welcomes the recent MHRA review of its patient and public engagement strategy and its plans to produce a PPI/E strategy.¹

Embracing regulatory innovation

Innovations in biomedical research need to be matched by appropriate ways to evaluate and regulate them. The COVID-19 pandemic has highlighted the ability of the MHRA to respond to emerging and dynamic public health challenges. New initiatives put in place by the MHRA to expand upon the current regulatory framework include the Innovative Licensing and Access Pathway (ILAP)² and increased regulatory flexibilities such as extending audit windows, deadline flexibilities and the prioritisation of COVID-19 products and trials.³ In partnership with NICE, the MHRA has also developed a scientific advice initiative, which allows those developing medical products to meet with NICE, MHRA and other experts to explore health technology assessments and relevant regulatory issues.⁴

The Academy also welcomes other recent actions by the MHRA - including the development of guidance statements for the use of innovative approaches such as real-world evidence⁵ - that indicate that they are willing to take an innovative stance on regulatory decision-making. The Academy has brought the life sciences community together to discuss the potential application of other contemporary approaches in the regulation and evaluation of medicines, including novel endpoints and outcome measures,⁶ complex innovative design (CID) trials⁷ and the use of new data sources.^{8,9} CID trials have played an influential role in the UK's R&D response to the COVID-19 pandemic, with prominent trials such as RECOVERY,¹⁰ REMAP-CAP¹¹ and PRINCIPLE¹² utilising 'platform' designs. The use of these designs could act as a springboard for their increased use for future trials where appropriate. It is important that regulatory processes are able to adapt and respond to the increasing use of novel trial designs and different forms of evidence.

While we can draw many positives from the UK regulation sector's response to the COVID-19 pandemic, we recognise that there were many challenges posed by the public health need to accelerate regulatory protocols. Moving forwards, we hope the sector can learn from both the

¹ Medicines and Healthcare products Regulatory Agency (2020). [How should we engage and involve patients and the public in our work](#)

² Medicines and Healthcare products Regulatory Agency (2021). [The MHRA Innovative Licensing and Access Pathway is open for business.](#)

³ Medicines and Healthcare products Regulatory Agency (2020). [MHRA regulatory flexibilities resulting from coronavirus \(COVID-19\).](#)

⁴ National Institute for Health and Care Excellence. [NICE-MHRA scientific advice.](#)

⁵ Medicines and Healthcare products Regulatory Agency (2020). [MHRA draft guidance on randomised controlled trials generating real-world evidence to support regulatory decisions](#)

⁶ Academy of Medical Sciences (2017). [Looking to the future: oncology endpoints](#)

⁷ Academy of Medical Sciences (2019). [Adaptive trials: acceptability, versatility and utility](#)

⁸ Academy of Medical Sciences (2018). [Next steps for using real world evidence.](#)

⁹ Academy of Medical Sciences (2018). [Our data driven future in healthcare](#)

¹⁰ [RECOVERY Trial](#)

¹¹ [REMAP-CAP Trial](#)

¹² [PRINCIPLE Trial](#)

successes and shortcomings in the response and translate this into improvements that last beyond the pandemic.

Streamlining and accelerating processes for innovative and emerging technologies

The Academy supports the implementation of pathways that could allow patient access to medicines and other innovations sooner without compromising on safety, such as those developed by the Accelerated Access Collaborative.¹³ The MHRA's existing accelerated pathways, such as the Early Access to Medicines Scheme, when combined with initiatives to improve uptake of innovations into the NHS, such as the Rapid Uptake Products programme, go some way to speeding up the adoption of innovation.

However, emerging innovations in medical research, including personalised medicine, genome-editing and data-driven technologies (such as artificial intelligence), may challenge traditional regulatory pathways, including existing accelerated pathways. With this problem in mind, the Academy recently held a roundtable discussion in collaboration with the MHRA on the topic of regulatory science, which explored how advances in this field may facilitate efficient regulation of current and emerging medical products. The report and findings of this roundtable are yet to be published, but we would be happy to share those with you once they are.

Market authorisation by the MHRA is only one step in ensuring patient access to new medicines. In order to streamline processes, accelerate evaluation and encourage innovation, MHRA and NICE protocols should be aligned where possible. Furthermore, collaboration between the MHRA, NICE and the NHS is vital to ensure effective and timely transitions through the market authorisation and health technology assessment process, and to encourage timely adoption.

Supporting effective international collaboration

Now that we are no longer part of the EMA system, MHRA market authorisation covers the UK population of 70 million people, a small fraction of the 450 million people living in the EU. There is therefore a risk that companies may deprioritise seeking MHRA authorisation to access larger patient populations for their licensed medicines.

International collaborations could provide an opportunity both to improve the MHRA's own regulatory processes, through information and expertise exchange, and to establish the UK as a priority country for companies seeking market authorisation by ensuring that the UK's regulatory system is aligned with those of other countries. Although these benefits might be attractive, ensuring patient safety and the robustness of regulatory processes must always be the priority when looking at the impact of potential new international collaborations. Collaborations should not be formed if they compromise these priorities, even if they may provide other benefits.

The UK's departure from the EU may offer some opportunities for the MHRA to be flexible in a way that would reduce the time taken for patients to access safe and effective health technologies. It will be necessary to also balance these potential benefits with the importance of retaining our strong and fruitful international partnerships alongside our ability to participate in and lead international trials. The Academy supports continued collaboration between the UK and EU Member States across all stages of research, development and innovation.¹⁴ Our regulatory systems should continue to enable this collaboration and should avoid creating unnecessary

¹³ Academy of Medical Sciences (2019). [Response to the All Party Parliamentary Group on Access to Medicines and Medical Devices consultation on the NICE Methods Review](#)

¹⁴ Academy of Medical Sciences (2021). [President's response to the announcement of a Brexit deal](#)

barriers. The Academy's Fellowship have previously voiced the opinion that regulatory harmonisation provides a strong platform for collaboration and commercialisation in health research.¹⁵ In addition, we are glad that the UK's association with Horizon Europe will allow participation successor to the EU's Innovative Medicines Initiative, a major public-private initiatives that foster collaboration among universities, industry, patients, and medical regulators to accelerate the development of medicines.¹⁶

The ICH Good Clinical Practice (GCP) guidelines¹⁷ already set out some international standards to ensure that trials can be compared across international boundaries. Alignment between nations provides several advantages, such as sped up assessment and adoption, preventing duplication of effort and reducing the economic barriers to innovation by the private sector. There are some areas where alignment is even more important, such as international trials conducted for the purposes of accessing large patient numbers, or in rare diseases where patient numbers within a single country may be low.

¹⁵ Academy of Medical Sciences (2015). [The Academy of Medical Sciences' response to the House of Lords Science and Technology Committee inquiry into influence of EU membership on UK science](#)

¹⁶ [Innovative Medicines Initiative](#)

¹⁷ [EMA ICH Good Clinical Practice guidelines](#)